

UNITED STATES PATENT AND TRADEMARK OFFICE

MAR - 7 2011

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

William M. Blackstone Akzo Nobel NV 903 St. Georges Rd Baltimore, MD 21210 In Re: Patent Term Extension Application for U.S. Patent No. 5,270,057

RE: FOLLISTIM®

Docket No.: 95E-

Dear Mr. Blackstone:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,270,057 for a period of 193 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till

Senior Legal Advisor

Office of Patent Legal Administration Office of the Associate Commissioner

for Patent Examination Policy

cc: Office of Regulatory Policy

Food and Drug Administration

10903 New Hampshire Ave., Bldg. 51, Rm. 6222

Silver Spring, MD 20993-0002

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Akzo Nobel N.V.

Request for Patent Term Extension

U.S. Patent No. 5,270,057

ORDER GRANTING

INTERIM EXTENSION

Akzo Nobel N.V., the current owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,270,057, filed an application for patent term extension under 35 U.S.C. § 156 on November 25, 1997. The original term of the patent is due to expire on March 20, 2011. The patent claims the active ingredient, recombinant human follicle stimulating hormone (hFSH), in the human drug product FOLLISTIM® which was approved by the Food and Drug Administration for commercial marketing or use on September 29, 1997. An extension of 193 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,270,057 is granted for a period of 193 days from the original expiration date of the patent.

David J. Kappas

March 4, 2011

Date

David J. Kappos

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office